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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FORD, JOHN K

ART UNIT PAPER NUMBER

3753

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38

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/895,936

Applicant(s)

Wisniewski + Leonard

Examiner

FORD

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/5/03 + 7/14/03
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-116, 118-123 is/are pending in the application.
- 4a) Of the above claim(s) 69-87, 90-95, 97-100, 102-104, 120-123 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 88, 89, 96, 101, 105-116, 118 and 119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Applicants' response of July 14, 2003 (Paper No. 37) has been carefully considered. Counsel correctly pointed out that Mr. Wu is not a named inventor in the current application and in every instance where Mr. Wu is mentioned in Paper No. 36, Mr. Leonidas Leonard (the other inventor) was, in fact, meant. However as recently as the year 2000 Mr. Wu and Mr. Wisniewski co-authored a publication entitled: "Scale-Down approach to Large Volume Cryopreservation of Biopharmaceuticals using the CryoCassette and CryoWedge. Applicants' assertion that the Examiner "believes that Applicants are withholding information about the Genentech device" is without support in this record.

It is a fact that in this prosecution, progressively, more and more information about the Genentech device has been provided by Mr. Wisniewski as he has been repeatedly asked questions about it. Problematic of this creeping disclosure, it is noted that the 1992 Wisniewski and Wu article was not originally provided to the Examiner by Applicants. Instead, a far less detailed description of the Genentech device was provided in the 1996 article by Wisniewski and Wu entitled "Large-Scale Freezing and Thawing of Biopharmaceutical Products". It was only after the Examiner required on his own a copy of a reference identified on page 59 of the aforementioned article that a copy of it was finally produced.

As time has gone on, continued questioning by the Examiner has led to Mr. Wisniewski revealing many more details about the Genentech device through declarations and statements in the record. In the face of all of this additional evidence produced by the Examiner's questions, counsel now asserts with no logic or reasoning

that applicants (Mr. Wisniewski and Mr. Leonard, who has not gone on record in any declaration) have fully complied with Rule 56, and that Examiner, in pursuing what has thus far been arduous but critically fruitful questioning, is outside his authority.

Applicants have refused to provide the Examiner with any sketch of the prior art discussed on page 2 of the specification leaving it to the Examiner to "imagine a device having fins that extend and contact the inner wall of the container...". This is not an appropriate response.

Regarding assertions of "inequitable conduct" counsel has clearly cast his own applicants' behavior in the worst possible light in an apparent attempt to end the Examiner's legitimate questions about the closest prior art in the case. The Examiner has no authority or interest in assessing the subjective intent of applicants in failing to have provided full disclosure of relevant information about the Genentech device at the start of prosecution. By the same token, the Examiner needs to have full disclosure of the Genentech device to properly consider the patentability of the current claims. But for Mr. Wisniewski's close connection to Genentech, and the 1992 article, the Examiner has no other reasonable source of information. Rule 56 and Rule 105, (MPEP 704.10) in particular, empower the Examiner to make inquiries and unfortunately Applicants have provided the information about the Genentech device in dribs and drabs over the course of years, leading to protracted questioning which is no more pleasant for the Examiner than for applicants. It is unfortunate that applicants have chosen this route

but the questioning would have long ago ceased if the relevant information was provided completely at the beginning of the prosecution.

This application was filed in 1997. Any delay in pursuing an appeal is entirely applicants' responsibility not the Examiner's.

Extremely relevant prior art is discussed in the specification under the heading "2. Description of the Prior Art" (page 1, line 22-page 2, line 17). Unfortunately the description is somewhat ambiguous. Carefully drawn sketches of this prior art (if no publication exists) have been required for years showing this prior art with enough details so as to permit meaningful comparison to what is claimed here.

Applicants have refused to provide such a sketch leaving it in Paper No. 37 (page 3, lines 3-16) for the Examiner to "imagine" such a device and arguing no recollection, non-materiality, and equivalent disclosures found in USP 2,441,376 and USP 2,129,572 (which latter references were unknown to applicants at the time they filed this application).

Interpretation of claim language

Applicants have argued that the terms "thermal bridge" and "biopharmaceutical product" are definite (Paper No. 28, pages 7-9). Applicants have stated that "thermal

bridge"(as found in claim 89) is definite and that the Examiner's reading is overly board.

The Examiner's broad reading of what constitutes a "thermal bridge" is consistent with the definition this term is given in the specification. See specification page 4, lines 20-24, and page 4, line 29-page 5, line 5. On page 15, lines 13-16 the following broad

definition is given: "The present invention is useful for both the cooling and heating of a medium. When the medium is frozen the thermal bridges help heat to be transferred into the medium." *out of the medium. When the medium is being heated the thermal bridges help heat*

The specification goes on to state:

"The medium can also be a gas being converted to a liquid or a liquid being converted to a gas. In these cases the liquid phase of the medium that collects between the fin and the structure will act as the thermal bridge to enhance conduction of heat between the fin and the structure."

Thus the Examiner's broad reading of a "thermal bridge" is consistent with the broad definition that this term enjoys in the specification. Thus, the term "thermal bridge" is clearly not limited to freezing but also applies to heating situations and, as defined in the specification, and includes an enhancement heat transfer due to geometry (e.g. the closeness of two surfaces) and/or the conductivity of the medium used in the device.

It is noted that claims 88-89 only claim "actively cooling" the annular wall of the vessel. They do not recite freezing of the "biopharmaceutical" and claim 88 does not recite any "active cooling" of the centrally disposed heat exchange structure.

Alleged proof of difference between Genentech device and current claimed device.

Applicant alleges on page 8 of Paper No. 28, beginning at the middle of the page, that no thermal transfer bridge will form in a device with too large a gap (presumably referring to the 1992 Genentech prior art from Basel, Switzerland). The "proof" of this alleged fact is offered in the form of a declaration by one of the inventors (Mr. Wisniewski). With regard to Exhibits B, C and D he states that the temperature distributions shown there "reasonably resemble" the actual temperature profile, "to the best of his knowledge".

There is no evidence that these are actual measured results (the best form of proof in this particular case) or are even computer generated results. No disclosure is given for the materials and sizes of the components depicted. No disclosure of the gap size is given in Mr. Wisniewski's analysis. No disclosure is given for how Mr. Wisniewski determined these curves. No calculations are shown. No factual supporting materials are given to support that Mr. Wisniewski's estimates or guesses at the temperature profiles are in fact reflective of reality. The proof as it stands is not convincing as will be elaborated upon below.

Particularly unconvincing in the Examiner's mind is Exhibit D, where ice has clearly bridged the distal end of the heat transfer fin and the inner side of the annular cooled wall.

At that point, Fourier's law of heat conduction essentially begins to take over, and the temperature profile as time goes on will begin to have linearly downward slope determined by the difference in temperature between the distal end of the fin and the inner side of the annular wall.

It is noted, for the record, that Figure 3b of the drawings depicts the temperature profile at some undisclosed time after immediately after cooling has been initiated. It is submitted that immediately after cooling is initiated, for the geometry shown in Figure 3b of the specification, the characteristic "peak-shaped" temperature profile depicted in Exhibits B and C will apply to Applicant's device, because of self-evident principles of heat transfer.

As stated by the Examiner in Paper No. 25, there is really no difference in the fundamental heat transfer physics which occurs in applicant's device of Figure 3B and that depicted in the 1992 publication.

The bridging will admittedly occur more quickly in a small gap than in a large gap, but the temperature profile once enough material is frozen in and around the gap will

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have a linear profile whose slope is entirely determined by the relative temperatures at the end of the fin and the inside of the wall.

Moreover this Examiner who holds a masters degree in Engineering from Princeton University, does not believe that there is anyone who can model or calculate these temperature profiles without the aid of sophisticated computers and/or experimental work. On this point see Kalhori & Ramadhyani "Studies on Heat Transfer From A Vertical Cylinder, With or Without Fins, Embedded in a Solid Phase Change Medium", page 44, second and third paragraphs. The processes of modeling natural convection and moving-front phase change occurring together with sub-cooling is, to the Examiner's knowledge, is state of the art or beyond the state of the art in numerical solutions on computers. If applicants know otherwise please submit appropriate proof.

Applicant's first and second declarations have been received (on February 21, 2002 and March 5, 2003, respectively). In addition, applicant and counsel have stated for the record (in at least SN 10/057,610) that they will not contact Genentech (Mr. Wisniewski's former employer) to obtain additional information about the prior art 1992 biopharmaceutical freezer that Mr. Wisniewski (and, apparently, Mr. Wu) developed during his employment at Genentech. In refusing the Examiner's request to obtain the relevant dimensions of this prior art device, counsel states that it is "unnecessary and goes beyond the duty owed to the Patent Office by an inventor or their representatives." The Examiner will not make any further inquiry in light of this refusal, as apparently it

would be fruitless. The tiresome inquiry has thus far yielded a few additional details from Mr. Wisniewski (e.g. the 1992 article and the 1996 Advanstar Reprint which were not originally submitted to the PTO, only the 1996 DMT article was, and the second declaration paragraph 8 admission that "I know that this distance was greater than 4 inches"), but has largely exceeded in wasted examination time what was extracted in terms of additional details about the prior art, with the exception of the 1992 article and the 1996 Advanstar equivalent.

First declaration

Paragraphs 1 – 4, no dispute.

Paragraph 5, the 1992 and its equivalent 1996 Advanstar publications were not disclosed to the PTO originally. Only a 1996 DMT article was disclosed which contains very few details of the prior art Genentech device. Only through the Examiner's inquiring was the 1992 article and its 1996 Advanstar equivalent made of record.

Paragraph 6, Mr. Wisniewski admits that he designed the internal heat transfer coil with fins for the Genentech device, the details of which he does not, now, recall. While the 1992 article does not explicitly discuss a "thermal bridge" there is nothing, which suggests one did not form. The absence of any specific discussion is not necessarily evidence that the phenomena did not take place. It is respectfully submitted that a thermal bridge would inherently form in the 1992 Genentech device because the

vessel wall during the chilling process will always be at a lower temperature than the central structure because the coldest coolant is directed to the jacket first and then the (now slightly warmed coolant) is directed to the central structure by virtue of the piping system clearly disclosed in the 1992 article.

Paragraph 7. Mr. Wisniewski's projections are no more than guesses of what the temperature distribution would be. It is respectfully submitted that these freezing phenomena are so complex that no human being including one with nearly 30 years of experience can accurately predict such results. Purporting to have such ability only diminishes one's credibility. One need not look far to see that the Examiner is correct. The Kalhori and Ramadhyani (K & R) article which involves solid phase change around a structure somewhat simpler than the 1992 Genentech device states:

"As will shortly become evident, the problem of phase change around an embedded vertical cylinder is a moving boundary problem in a complex geometry. An analysis of the problem would involve the solution of the energy equation coupled with hydrodynamic equations in the liquid phase. This is a challenging task that is amenable **only** to a numerical solution. Consequently, in addition to providing information of utility in the design of thermal storage units, data from the present study could be useful in validating a numerical solution of the problem." (emphasis supplied).

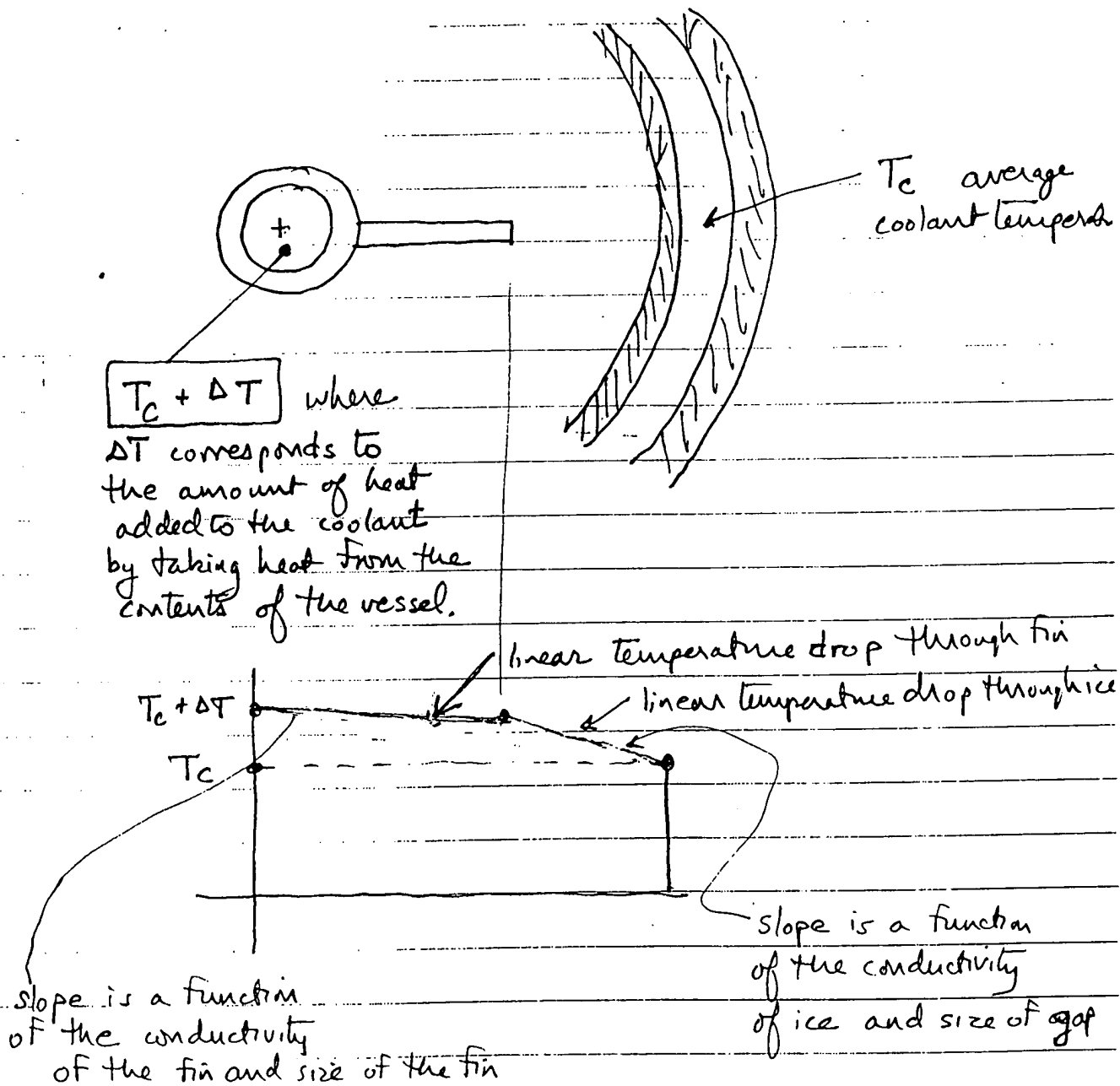
Thus, researchers, other than Mr. Wisniewski, state that accurate modeling of phase change heat transfer in tanks with finned element such as shown in Figure 3 of the K & R article can only be done by computers or by direct empirical measurement.

For this reason the Examiner does not find Mr. Wisniewski's thought experiments as credible evidence of what the actual temperatures are in the 1992 Genentech device. The Examiner has repeatedly asked Mr. Wisniewski to test this prior art, or a reasonable facsimile of it, using temperature transducers and Mr. Wisniewski has refused thus far.

Moreover, Exhibit B incorrectly assumes the temperature in the pipe is the same as the temperature in the jacket. This is an incorrect assumption and will necessarily lead to inaccurate conclusions. The temperature in the pipe is a complex function of the initial temperature of the coolant before it passes through the jacket, the temperature of the liquid in the container and the flow rate of the coolant among other variables. As explained above, and as shown in Figure 1 (page 134) of the 1992 article, the coolant goes from the refrigeration system to the jacket and only after exchanging heat with the contents of the vessel (and thereby acquiring some higher temperature) does it pass into the central structure where it necessarily must have a higher temperature than the coolant in the jacket. Thus, Mr. Wisniewski's thought experiments are flawed because they are based on incorrect boundary conditions.

Paragraph 8, Exhibit C, like Exhibit B is simply a guess at what the temperature distribution actually is. As stated with respect to Exhibit B, the temperature distribution must either be measured or generated by very sophisticated computer programs, which have had their validity checked against measured data. Mr. Wisniewski has not done this. The results are not credible, for this reason.

Paragraph 9, Exhibit D is clearly erroneous, beyond the reasons stated above. Once the ice bridges the entire gap to a significant extent, the temperature distribution through a solid ice (non-moving interface) is relatively easy to predict analytically and Mr. Wisniewski's analysis can be shown to be incorrect. The correct analysis to a first approximation, which can be done by anyone of ordinary skill in the art, is given below:



Paragraph 10, these allegations are not supported by valid factual materials. Mr. Wisniewski's guesswork even in declarative form is simply no substitute for real evidence. Neither he nor any other person on the planet is in a position to properly guess at the actual temperature distribution. The analysis in paragraph 10, is true no matter how large the gap is. Initially heat will be transferred from the fluid in the gap to both the fin and the wall, regardless of gap size. This process will persist longer in a large gap than a small gap but the physics of the problem is the same regardless of gap size. Applicant is free to rebut this analysis with real evidence (i.e. test results) not idle speculation.

Second Declaration

Paragraphs 1 – 4, no dispute.

Paragraph 5, Mr. Wisniewski did not disclose the 1992 article or its 1996 equivalent until the Examiner required its disclosure. Moreover Mr. Wisniewski continues to co-write articles with Mr. Wu including an article written in 2000 entitled "Scale – Down Approach to Large Volume Cryopreservation of Biopharmaceuticals Using the CryoCassette and CryoWedge" (available at Integrated Biosystems website). Mr. Wisniewski has not contacted Mr. Wu to see what he remembers about the

Genentech device in spite of repeated requests by the Examiner for additional information.

Paragraph 6, appears to refer to an office action in another application. It is on this basis disregarded.

Paragraphs 7 and 8, for the reasons stated previously, it defies imagination that Mr. Wisniewski could remember the tip to wall distance as greater than 4 inches yet recollect nothing else about the prior art including the approximate size of the vessel (i.e. whether or not he could get his arms around it or pick it up etc.). It is also not understood why he doesn't contact Mr. Wu with whom he co-wrote an article as recently as the year 2000 to see what he remembers of the Genentech device, nor is understood why Genentech would not cooperate given that Genentech is a customer of Integrated Biosystems according to John H. Brown the president and CEO of Integrated Bio Systems (in an article from the wall Street journal available at Integrated Biosystems website). Counsel has gone on the record (Paper No. 8, page 2 in SN 10/057,610) stating that Genentech is a competitor of Integrated Bio system, an allegation, offered as fact, that does not appear to comport with reality. The remainder of the factual allegations in paragraph 8, which reiterate those made in the first declaration, are not credible for the reasons enumerated in the Examiner's critique of the first declaration.

Finally, as demonstrated by the article in BioPharm, Vol. 15, No. 5, May 2002 (available at Integrated Biosystems website), Mr. Wisniewski and his assignee have very sophisticated software and hardware at their disposal to perform the testing that the Examiner believes is required to establish the truth of the matter asserted. On page 4 of that article a CryoWedge 20 is disclosed which appears to be used to do the sophisticated type of testing that has been studiously avoided in these applications. If Mr. Wisniewski's hand drawn sketches were accurate it is submitted that Integrated Biosystems would have no need for the Cryowedge 20 or any of the other sophisticated models and programs discussed in that article. It is also noted that Genentech is disclosed to be a customer of Integrated Biosystems not a competitor as alleged by counsel in his latest remarks (Paper No. 8, page 2, paragraph 2, line 6 of SN 10/057,610) calling the Genentech prior art "a competitive system." Note John Brown, in the Wall Street Journal interview, called Genentech a customer of Integrated Biosystems. Each of these units according to Mr. Brown can cost upwards of \$ 40,000 - \$100,000. With those kinds of numbers and the sophisticated modeling and equipment to perform experiments that exist at Integrated Biosystems the Examiner is completely perplexed with Mr. Wisniewski's and counsel's representations that the PTO has to accept Mr. Wisniewski's hand drawn sketches based on speculative guesswork involving dubious assumptions as the best evidence applicants' possess. Clearly applicants are in a position to present much more legitimate evidence of actual temperature profiles in both their own device and in the prior art than what they have disclosed here.

Given all of the other information that has been given which is incorrect the Examiner does not see how it is possible for Mr. Wisniewski to remember that the fin tip to wall distance was greater than 4 inches yet fail to recall any other relevant dimension of the prior art (with the same degree of imprecision) including the overall size of the tank. It does not seem plausible to the Examiner. Paragraph 8 is contradicted by the 1992 article where it is explicitly states that the fins were there to form compartments. Mr. Wisniewski's statements that they were only there to increase heat transfer contradict the 1992 article and are not credible. The conclusion, unsupported by any facts, that no thermal bridge was formed in the 1992 Genentech device is similarly not credible.

In paragraph 9, Mr. Wisniewski has simply refused to provide a sketch of the admitted prior art in the parent applications as required numerous times throughout the prosecution. Instead USP 2,441,376 and USP 2,129,572 (references that Mr. Wisniewski was not even aware of at the time that the parent applications were written) are offered instead. Please comply with the sketch requirement. These two references do not correspond to what is disclosed to be the prior art in col. 1, line 33 – 47 of USP 6,196,296, counsel's and applicant's statements to the contrary notwithstanding. The Examiner did not ask about the prior art where the fin was attached to both walls. The Examiner asked for a specific sketch and it has not been produced.

Finally, in paragraph 10, Mr. Wisniewski simply states a conclusion without any legitimate testing to support it. Once the medium is frozen in the gap, the Genentech device will have a "thermal bridge" formed given how that term is defined in the current specification and that of the parent applications.

Definition of biopharmaceutical

The definition of "biopharmaceutical product" offered by Burman, Lawlis, Jr. and Vetterlein is fine as far as it goes but it appears to conflict with the one offered in the specification because some of the examples given in the specification, most notably "buffer solutions" do not fit the definition offered up by Burnam, Lawlis, Jr. and Vetterlein. On this last point, applicant argues that "blood or other body fluids" are buffer solutions and "are indeed biopharmaceutical products due to mixtures of weak acids and base present in them" (remarks, sentence bridging pages 11 and 12). The argument is unconvincing. The Examiner has never heard of "blood" being a known as a buffer solution. Buffer solutions, it is respectfully submitted, are known in the art to be weak acids or bases of known pH used in chemical laboratories. If blood was a known "buffer" why is it (along with "plasma") given as a separate example of a "biopharmaceutical product" in the list found on page 7, lines 4-9?

In response to this action please submit factual materials to support the assertion that "blood" is known to those of ordinary skill to be an example of a "buffer solution".

More problems with prior art

Counsel maintained that the 1996 DMT article was less than a year old and was the inventors' own work and thus did not constitute prior art under any section of 35 USC 102 and hence under 103 in the prosecution of some of the parent applications. The Examiner then required a copy of the 1992 article which clearly constitutes prior art under 102(b) and is materially more detailed as to the structure of the heat transfer system than the 1996 DMT article. In response to that request applicant (in SN 08/895,782) sent yet another 1996 article (published by Advanstar) however on the first page of the text of that article (see footnote at bottom) it is disclosed that the Advanstar article was previously published in February of 1992.

The Examiner also needs and exact publications date (month and day) for each of the 1996 articles (Advanstar and the Drug Manufacturing Technology Services, Vol. 2) to ascertain their prior art status as to this application. It is noted that both 1996 publications have authorship which differs from the current inventive entity and hence would be prior art under 102(a) and the case law interpreting "another". If counsel continues to insist the 1996 publications are not prior art, please address in detail his reasons why they are not. Please address some comments of the differing inventive entity vis-à-vis the authorship entity, and why they should not be treated as disparate under 35 USC 102(a).

On pages 2 and 3 of the specification under a section entitled "Description of the Prior Art" applicants appear to disclose that liquids, possibly biopharmaceuticals, have been heated and cooled in containers, which have structures comprising "extensions of the container or any structures in the container". Fins are mentioned specification under a section entitled "Description of the Prior Art" applicants appear to disclose that liquids, possibly biopharmaceuticals, have been heated and cooled in containers which have structures comprising "extensions of the container or any structures in the container". Fins are mentioned specifically but are "typically attached to the container or an internal structure at only one point".

Full disclosure of this prior art is needed. If applicant does not have a publication, a carefully drawn sketch with meaningful legends and explanations is required. Disclosure of what processes. (e.g. heating, cooling, freezing etc.) have been performed in this acknowledged prior art described on pages 2 and 3 of the specification is required as well as what fluids (e.g. biopharmaceuticals etc.) have been processed in the acknowledged prior art container.

Moreover the 1992 disclosure of Wisniewski and Wu does not disclose how close to the wall of the container the heat transfer fins extended, the dimensions of those fins (length, width, height and thickness), the diameter of the container and the volume of the container. Because applicants are in possession of this information and the

examiner has no other reasonable way to obtain it, a requirement under Rule 1.56 and Rule 1.105 is set forth here. Timely submission of this information will permit an orderly examination and will avoid the Board having to require such information under Rule 1.196(d) should an appeal be forthcoming. Applicant must know this information because he apparently used it to generate Exhibits B, C and D.

Claims 88, 89, 96, 101, 105-116, 118 and 119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out distinctly claim the subject matter which applicant regards as the invention.

The term "thermal bridge" as used in claims 88, 108 and 114 of this application is vague. It appears to denote any area where one thermally conditioned surface is in greater proximity to another surface (either itself thermally conditioned or unconditioned) than it is to other surfaces within the device. Is that a correct understanding? If not, why not? If not, what is it? It is submitted that the entire content of fluid in the tank will conduct heat, and that any conditioned structure within the container will conduct heat out of the medium if it is cooler than the medium. The opposite is true for a heated surface.

The term "biopharmaceutical product" as it is used in this application is ambiguous and hence its use in claims 88, 108 and 114 is also the source of ambiguity. In contrast with what may be accepted "biopharmaceutical products" such as a product

derived from biological sources that has an intended therapeutic application and whose manufacturing is or will be regulated by pharmaceutical or veterinary regulator agencies (see "132 declarations in Paper No. 17), in the specification applicants state that the present invention can be used to "freeze and preserve a variety of biopharmaceutical products, including but not limited to proteins, cells, antibodies, medicines, plasma, blood, buffer solutions, viruses, serum, cell fragments, cellular components, and any other biopharmaceutical product".

Many of the purported biopharmaceuticals on applicants' list in the specification are not normally considered biopharmaceuticals on applicants' definition (offered up in the '132 declarations in Paper No. 17) above. For example, buffer solutions are acids or bases-dissolved in water not derived from biological sources nor regulated by FDA to the Examiner's knowledge. Blood, per se, such as is drawn from the general population by the Red Cross would not appear to be a biopharmaceutical by affiant's definition yet it appear on applicants' list. On page 133, col. 1, fourth full paragraph, of the 1992 Wisniewski and Wu prior art (Paper No. 20), it states that "buffer salts" can be components of a biopharmaceutical product but it appears the "buffer salts" are not themselves a biopharmaceutical product. "Medicines" are simply understood to be drugs or other agents used to treat disease or injury. They need not be derived from biological sources. What is vital to this examination is to know with reasonable particularity what chemicals when placed in applicants' tank would infringe the claims. Under applicants' expansive definition of biopharmaceuticals into the specification it

would appear that many conventional organic and inorganic solutions (e.g. buffer solutions) would be included-against what affiant Arathoon, Burman, Lawlis and Vetterlein (Paper No. 17) would consider to be the reasonable limits of the word. On the other hand, orange juice recently shown to have measurable effects against certain forms of cancer, was suggested by counsel to not seriously be considered a biopharmaceutical. The Examiner disagrees. If buffer solutions are considered to be biopharmaceuticals and blood, per se, drawn from the general population a biopharmaceutical, it doesn't seem reasonable to exclude orange juice. The chances of the FDA regulating "buffer solutions" as pharmaceutical in the future would be about on par with the chances of the FDA regulating orange juice as a biopharmaceutical in the Examiner's opinion. If the definition now includes orange juice based on new research showings its anticancer properties and possible future regulation by the FDA, then applicants' use of the word biopharmaceutical seems to include an ever growing and somewhat amorphous list of chemicals what would be perpetually changing as new research was done to show therapeutic properties to products produced by biological processes such as photosynthesis, fermentation and biological agents such as herbs, roots and compound which are essentially the products of nature. It is impossible to know which of these will be regulated by the FDA in the future given the vicissitudes of government regulation. The term as it is used in the application is deemed by the Examiner to be one that violates the tenets of 35 USC 112, second paragraph, in that the metes and bounds of the claims cannot be established with the requisite clarity required by the statute and are subject to change based on future FDA actions. The

would-be infringer would have no clear way to determine infringing behavior, to put it another way. Infringement would be constantly changing depending on what the FDA decided to regulate as a biopharmaceutical. It is noted that the FDA regulates the handling and composition many food items, but that doesn't transform them into biopharmaceuticals even if those food items have some therapeutic benefit. The definition offered by the declarants appears to be unworkable in the Examiner's opinion and that offered in the specification ambiguous.

The declarations under Rule '132 by Arathoon, Burman, Lawlis and Vetterlein (see Paper No. 17) all appear to define "biopharmaceutical products" much more narrowly than the expansive definition given in the specification. For example, the Examiner knows of no biologically sourced "buffer solution" which in and of itself is regulated by the FDA. Moreover, if there were such a solution, why would it freeze any differently than a buffer solution not regulated by the FDA nor biologically sourced? It is noted that there is a tremendous variety of "biopharmaceutical products" in applicant's list some of which are very large: cells (e.g. blood etc.) whereas others are millions if not billions of times smaller (e.g. viruses or salt ions in a buffer solution). It is submitted that the freezing characteristics of solutions at these two extremes would be extremely different. Blood would probably freeze more in the manner of orange juice or milk given its nearly macroscopic cellular nature whereas virus in a suitable buffer solution or water would freeze in the manner of pure or salty water. Affiant Arathoon, Burman, Lawlis and Vetterlein all state in their conclusions that Cothorn, Nakamura and Morrison

(disclosing orange juice, solid particles in a liquid carrier and milk, respectively) do not suggest or teach devices or methods useful in processing biopharmaceutical products. Lacking in any of the declarations is any supporting reasons or analysis to show why declarant Arathoon, Burman, Lawlis and Vetterlein hold this opinion common to all of them. None of the affiant have provided any facts to support such a sweeping conclusion. Moreover Applicants' response as well as the declarations under Rule'132 have failed to reconcile the definition of "biopharmaceutical products" stated in the declarations with the disclosure of the chemicals and blood products, medicines, buffers etc. offered up as examples of biopharmaceutical products clearly encompasses more chemicals than Affiant' declarations under Rule '132. To the extent that the Rule '132 declarations define the term 'biophrmaceutical product" more narrowly than what is disclosed in the specification, the declarations serve to heighten the ambiguity of the disclosed and claimed "biopharmaceutical products" and what the limits (metes and bounds) of that terminology is to have as claim limitation. Moreover, in regard to the cited prior art, nothing in the declarations has addressed why one designing freezing equipment of the chemicals disclosed in the specification would not look to the art of freezing water, orange juice or solids suspended in liquids. The declarations under 37 CFR 1.132 (Paper No. 17) are not convincing for these reasons.

PRIOR ART REJECTIONS

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 88,89,96,105,108-110,112-115,118 and 119 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the 1992 Wisniewski and Wu publication.

The 1992 Wisniewski and Wu research paper appears to disclose every feature of the claimed invention including heat exchange members (i.e. fins) in close spaced proximity to the interior surface of the container. To the extent that the distance between the tip of the fin and the wall of the container is quantified by the phrase "in close spaced proximity", the reference appears to answer to the limitation. See Figure 1 and the description thereof found on pages 134 and 136. Note page 135 should follow page 136 and was apparently printed out of order. The Examiner did not catch this error when he examined SN 08/895,782.

There is no explicit disclosure of any ice bridge in the 1992 Wisniewski and Wu research paper (if that what is being claimed in the phrase "thermal transfer bridge", however see specification, page 5, lines 10-13, for apparently inconsistent definition: when the medium is being heated, after being frozen, the ice in the "gap" claimed between the tips of the fins and the wall of the container melts quickest leaving liquid in that "gap", hence it would appear that "thermal transfer bridge" is a much broader term than simply an ice bridge) formed between the tips of these fins and the interior wall of the container and no explicit disclosure of how close to the container wall these heat transfer fins extend, although they much extend far enough to define "compartments" between the fins (1992 Wisniewski and Wu research paper, page 136, first full paragraph).

The thermal bridge of ice will inherently form between the tip of the heat transfer fins and the interior of the container because they are the closest points to one another and both are actively cooled by circulating cooled silicon oil. Closely spaced cooled surfaces are known by those of skill in the refrigeration art to form ice bridges when a liquid is being frozen into a solid.

As evidence to support the Examiner's statement the closely spaced cooled surfaces will inherently form ice bridges (see MPEP 2112-2112.02, dealing with inherency, incorporated here by reference), the reader is referred to Voorhees USP

983,466, page 1, col. 2, line 97-page 2, col. 1 line 5 (Voorhees is not relied upon explicitly here, see MPEP 2131.01, sub-section III), wherein it states:

“Whether ice forms in single cakes about several freezing elements or forms in a single cake inclosing a plurality of such elements depends upon the spacing of the several freezing elements from each other. In the first instance of course, ice forms separately about each freezing element, but if these elements be **close together** the ice surrounding these elements will soon **coalesce into a single cake**; and after this has occurred freezing will go on from the surface of the combination cake so formed.” (Emphasis supplied).

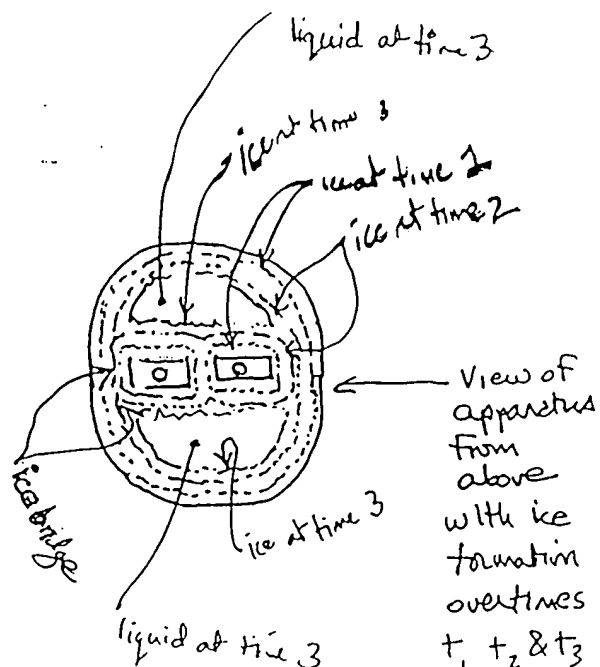
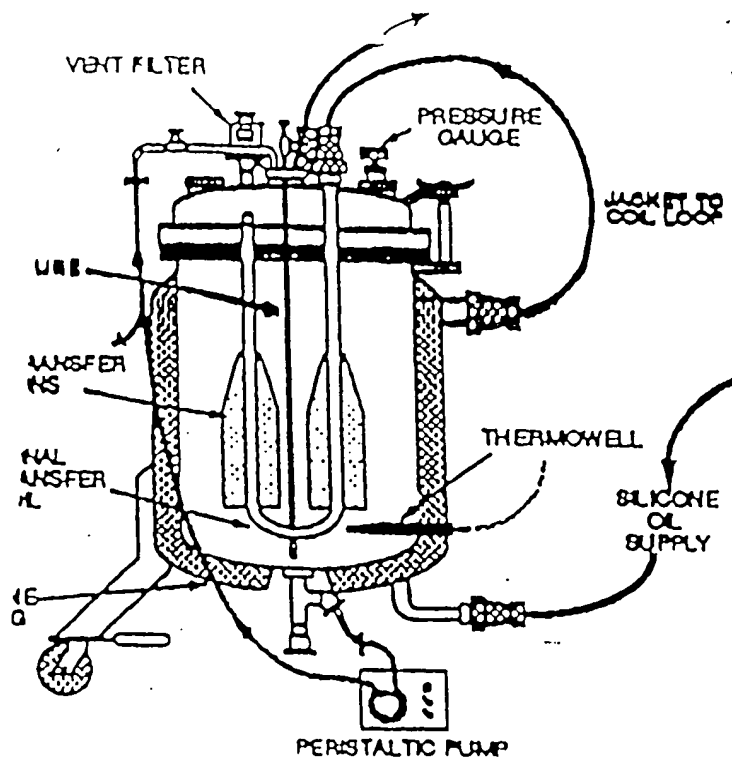
Furthermore, Voorhees, page 2, col. 1, lines 14-21 states:

“I have shown a number of other elements so spaced relatively as to form a single cake 15 of length comparable to cakes formed in plate processes. Of course if the **freez-ing were continued indefinitely the cakes 12,13,14 and 15 would eventually coalesce and freeze to the sides of the tank...**”

It is evident that ice will build up on the heat exchanger and walls of the vessel shown in Figure 1 of 992 Wisniewski and Wu research paper, during the freezing phase, until they bridge as shown in the diagrams below, a fact that can be established by basic scientific principles.

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Burroughs et al. USP 3,318,105 illustrates the phenomena. As is clearly seen in Figs. 1A—1C ice builds up evenly on cooled surfaces and even as the top surface freezes the ice coating on the submerged surfaces continues to build up more or less evenly. The same type of analysis is disclosed by Finnegan USP 2,129,572, illustrating that the time required to freeze a substance varies “approximately as the square of the thickness of such substance” with slower freezing generally leading to undesirable concentration effects (what applicants and the 1992 Wisniewski and Wu research paper refer to as “cryoconcentration”). Finnegan, like the 1992 Wisniewski and Wu research paper, discloses the use of heat exchanger fins (projecting inwardly from the exterior wall of the container in the case of Finnegan) to form compartments within the tank to speed the freezing process. Finnegan illustrates a series of dotted lines how the freezing process over time in various geometries of heat exchange fins. Applying this same science (illustrated by Burroughs and Finnegan) to the system disclosed by 1992 Wisniewski and Wu research paper yield the results illustrated on next page for the system disclosed by the 1992 Wisniewski and Wu research paper in Figure 1.



Even if the 1992 Wisniewski and Wu research paper is deemed not to disclose heat exchanger fins "in close spaced proximity" to the container wall, to have extended the fins in Figure 1 of the 1992 Wisniewski and Wu publication to a point "in close spaced proximity" to the interior surface of the container in order to advantageously increase the rate of heat transfer and "divide the tank volume into compartments to decrease the freezing and thawing time and to reduce cryoconcentration effects" (1992 publication, page 136, col. 1, first full paragraph) would have been obvious to one of ordinary skill in the art.

The examiner submits that the fins in Figure 1 of the 1992 Wisniewski and Wu publication are already in spaced proximity to the interior wall of the container such that substantially discrete compartments are formed (see page 136, col. 1, first full paragraph) an effect that would be enhanced if the fins were further extended to a point closer to the interior wall of the container.

Moreover, larger fins would increase the amount of surface area for heat transfer, giving an added advantage. On page 136 of the 1992 Wisniewski and Wu publication it states that the "fin's length, thickness and shape were designed to maintain **efficient heat transfer** during freezing and thawing." (Emphasis supplied). It is not open to any serious debate that larger, thicker, fins that extend to points closer to the interior wall of the container are more efficient heat transfer vehicles than smaller, thinner fins that do not extend to points closer to the interior wall of the container.

The 1992 Wisniewski and Wu publication states on page 136: " The heat transfer fins were configured to divide the tank into compartments to decrease the freezing and thawing time and to reduce cryoconcentration effects. Compartmentation of the tank is especially effective for maintaining liquid in a static state to minimize cryoconcentration". (Emphasis supplied). The fins are designed to maintain "efficient heat transfer during freezing and thawing" (a page 134, col. 2, 1992 Wisniewski and Wu publication). Figure 1 (page 134) of the 1992 Wisniewski and Wu publication clearly shows heat transfer fins extending outwardly from the internal heat transfer coil towards the interior wall of the container. Extending the fins further outwardly to aid in the formation of compartments to minimize cryoconcentration would have been another motivation to one of ordinary skill in the art to make the same modification to one of ordinary skill in the art to make the same modification.

Claims 88, 89, 96, 105, 108-110, 112-115, 118 and 119 are rejected under 35 USC 103 (a) as obvious over the 1992 publication by Wisniewski and Wu as applied to claims 88, 89, 96, 105, 108-110, 112-115, 118 and 119 above and further in view of : Euwema (USP 3,550,393), Cothorn et al. (USPN 5,535,598), the 1986 Kalhori and Ramadhyani article entitled "Studies on heat transfer from a vertical cylinder, with or without fins, embedded in a solid phase change medium" (references 29, on page 140 of the 1992 article by Wisniewski and Wu), Morrison and Nakao.

Euwema discloses ice bridges forming at the ends of vanes 36 and 38 when wall 10 is cooled by a refrigerant. See column 3, lines 4-19. The ice is shown at 18 (Figure 1) and rapidly bridges the gap between the tips of vanes 36 and 38 and the cooled surface 10 of the refrigeration device (Figure 2) in much the same manner that applicants disclose in their specification with regard to ice forming in the gap between the tips of their fins 8 and the inner wall of their container. Euwema's ice divides the regions on either side of vanes 36 and 38 into separate compartments to facilitate improved heat exchange with the liquid in those compartments. In other words, the ice bridges in Euwema prevent the fluids in the compartments on either side of vanes 36 and 38 from intermixing in much the same manner that the 1992 publication by Wisniewski and Wu discusses is a desirable feature in their invention (see the 1992 publication by Wisniewski and Wu, page 136, first full paragraph – "The heat transfer fins were configured to divide the tank volume into compartments to decrease the freezing and thawing time and to reduce cryoconcentration effects").

Likewise, Cothorn et al teaches (Figures 1-3) a jacketed tank (Figure 2) similar to applicants and fin-like heat exchanger formed with plates that divide the interior of the tank into a number of compartments by spanning nearly the entire tank to areas very close (close spaced gaps) to the sidewalls of the tank (in much the same manner applicants disclose, albeit in a square tank as opposed to a round tank). These large heat exchanger plates provide great surface area for improved freezing as discussed by Cothorn in column 7, lines 46-52. In Cothorn, having these closely spaced gaps

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between the distal ends of the immersed heat exchanger and the walls of the jacketed tank permits the heat exchanger to be withdrawn easily for cleaning and reduces the need for tight manufacturing tolerances in the immersed heat exchanger such as might be encountered in trying to make the immersed heat exchanger fit tightly into the tank and form fully non-communicating compartments.

The 1986 Kalhori and Ramadhyani article "Studies on heat transfer from a vertical cylinder, with or without fins, embedded in a solid phase change medium " (reference 29, on page 140 of the 1992 article by Wisniewski and Wu), like applicants have disclosed in Figures 1 & 2 of their drawings, shows in Figure 3 a "spur-tube" type heat exchanger with six heat transfer fins welded to it in a manner almost identical to what applicants show in Figures 1 and 2 of the current application. The finned heat exchanger as shown is immersed in a container of paraffin and the melting and freezing processes were studied in great detail with a material, paraffin, of known characteristics. See the abstract of this article on the first page. Again, fins that span nearly the entire interior of the container were found to be especially effective, with a host of definitive technical data presented (that is unnecessary to discuss here) showing the virtues of these large fins improving heat exchange. See last sentence of article – "In view of the superior heat transfer characteristics, the finned cylinder is a much better choice for the design of a practical thermal storage unit." (Emphasis supplied).

Morrison also teaches that fins 7 spanning nearly the entire interior of a container (which container is believed to be shown in phantom lines in Figure 1) "insure maximum heating or cooling surface so that operation of the device may be carried out with facility" (Morrison, column 1, lines 8-13).

Finally, Nakao teaches metallic fins 5 spanning nearly the entire interior of a container having a phase-change material therein. A relatively small gap exists between the end of these fins and the wall of the container. These fins greatly aid in the transfer of heat introduced at, and removed from, the periphery of the container.

In view of each of the above teachings, it would have been obvious to one of ordinary skill in the art to have extended the fins of the prior art disclosed in the 1992 article by Wisniewski and Wu to substantially the inner periphery of the container, leaving a small gap to permit the heat exchanger to be removed for cleaning (as is disclosed to be necessary in the 1992 article by Wisniewski and Wu on page 136). Extended the fins to substantially the inner periphery of the container would:

a. Improve heat transfer by increasing heat transfer surface area as taught by Cothorn, Kalhori & Ramadhyani, Morrison, Nakao and

b. Improve "commpartmentation" by forming ice bridges as explicitly taught by Euwema.

Claims 88 and 89 are rejected under 35 USC 103 (a) as being unpatentable over any of the prior art as applied to claims 88 and 89 and further in view of Cothern (USP 5,535,598).

Cothern in column 7, line 54-column 8, line 8 teaches various controls for controlling both rate and cooling direction in a freeze container by varying refrigerant flow in the various portions of the device. To the extent that the system disclosed by applicants in Figures 1 & 2 can accomplish the functions set forth in the claims, it would have been obvious to have configured the 1992 Wisniewski and Wu prior art with suitable controls to achieve the same end (those controls being broadly taught by Cothern). Since applicants' own specification is virtually devoid of how these functions are accomplished it must be surmised that obtaining these results must be within the skill of those skilled in the refrigeration art.

Claims 96, 105-110, 112-115, 118 and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of the 1992 publication by Wisniewski and Wu and the 1986 Kalhozi and Ramadhyani article.

The 1992 Wisniewski and Wu research paper appears to disclose every feature of the claimed invention including heat exchange member (i.e. fins) in close spaced proximity to the interior surface of the container. It lacks a "spur tube" type cooler in the

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center. See Figure 1 and the description thereof found on pages 134 and 136. Note page 135 should follow page 136 and was apparently printed out of order. The Examiner did not catch this error when he examined SN 08/895,782.

There is no explicit disclosure of any thermal ice bridge in the 1992 Wisniewski and Wu research paper (if that what is being claimed in the phrase "thermal transfer bridge", however see specification, page 5, lines 10-13, for apparently inconsistent definition: when the medium is being heated, after being frozen the ice in the "gap" claimed between the tips of the fins and the wall of the container melts quickest leaving liquid in the "gap", hence it would appear that "thermal transfer bridge" is much broader term than simply an ice bridge) formed between the tips of these fins and the interior wall of the container and no explicit disclosure of how close to the container wall these heat transfer fins extend, although they must extend far enough to define "compartments" between the fins (1992 Wisniewski and WU research paper, page 136, first full paragraph).

The thermal bridge of ice will inherently form between the tip of the heat transfer fins and the interior of the container because they are the closest points to one another and both are actively cooled by circulating cooled silicon oil. Closely spaces cooled surfaces are known by those of skill in the refrigeration art to form ice bridges when a liquid is being frozen into a solid.

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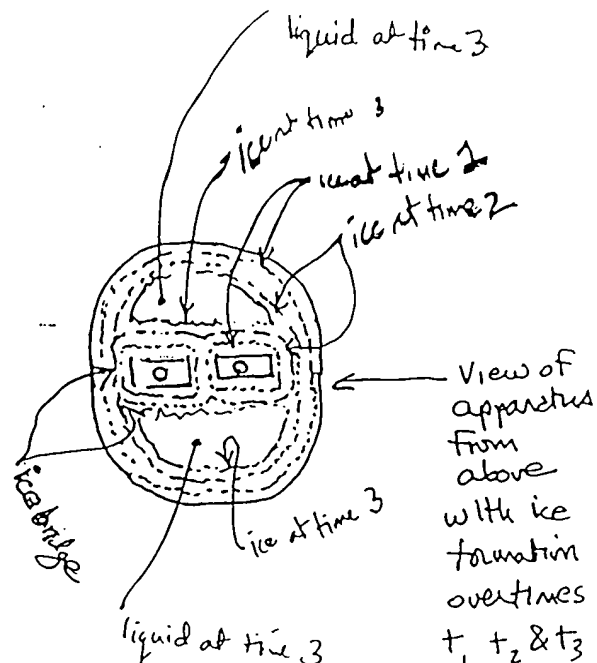
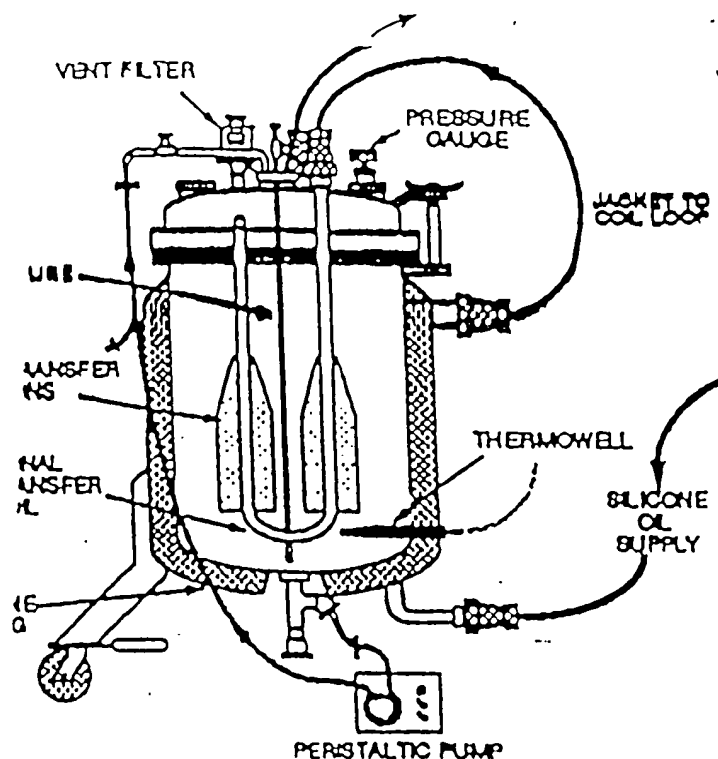
As evidence to support the Examiner's statement the closely spaced cooled surfaces will inherently form ice bridges (see MPEP 2112-2112.02, dealing with inherency, incorporated here by reference), the reader is referred to Voorhees USP 983, 466 page 1, col. 2, line 97-page 2, col. 1, lines 5 (Voorhees is not relied upon explicitly here, see MPEP 2131.01, sub-section III), wherein it states:

"Whether ice forms in single cakes about several freezing elements or forms in a single cake enclosing a plurality of such elements depends upon the spacing of the several freezing elements from each other. In the first instance of course, ice forms separately about each freezing element, but if these elements be **close together** the ice surrounding these element will **coalesce into a single cake**; and after this has occurred freezing will go on from the surface of the combination cake so formed" (Emphasis supplied).

Furthermore, Voorhees, page 2, col. 1, lines 14-21 states:

" I have shown a number of other elements so spaced relatively as to from a single cake 15 of length comparable to cakes formed in plate processes. Of course if the **freez-ing were continued indefinitely the cakes 12, 13, 14 and 15 would eventually coalesce and freeze to the sides of the tank...**"

It is evident that ice will build upon the heat exchanger and walls of the vessel shown in Figure 1 of 1992 Wisniewski and Wu research paper, during the freezing phase, until they bridge as shown in the diagrams below, a fact that can be established by basic scientific principles. Burroughs et al. USP 3,318,105 illustrates the phenomena. As is clearly seen in Figs. 1A-1C ice builds up evenly cooled surfaces and even as the top surface freezes the ice coating on the submerged surfaces continues to build up more or less evenly. The same type of analysis is disclosed by Finnegan USP 2,129,572, illustrating that the time required to freeze a substance varies "approximately as the square of the thickness of such substance" with slower freezing generally leading to undesirable concentration effects (what applicants and the 1992 Wisniewski and Wu research paper refer to as "cryoconcentration"). Finnegan, like the 1992 Wisniewski and Wu research paper, discloses the use of heat exchange fins (projecting inwardly from the exterior wall of the container in the case of Finnegan) to form compartments within the tank to speed the freezing process. Finnegan illustrates using a series of dotted lines how the freezing process progresses over time in various geometries of heat exchange fins. Applying this same science (illustrated by Burroughs and Finnegan) to the system disclosed by 1992 Wisniewski and Wu research paper yield the results illustrated on the next page for the system disclosed by the 1992 Wisniewski and Wu research paper in Figure 1.



Even if the 1992 Wisniewski and Wu research paper is deemed not to disclose heat exchanger fins "in close spaced proximity" to the container wall, to have extended the fins in Figure 1 of the 1992 Wisniewski and Wu publication to a point "in close spaced proximity" to the interior surface to the container in order to advantageously increase the rate of heat transfer and "divide the tank volume into compartments to decrease the freezing the thawing time and to reduce cryoconcentration effects". (1992

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publication, page 136, col. 1, first full paragraph) would have been obvious to one of ordinary skill in the art.

The examiner submits that the fins shown in Figure 1 of the 1992 Wisniewski and Wu publication are already in spaced proximity to the interior wall of the container such that substantially discrete compartments are formed (see page 136, col. 1, first full paragraph) an effect that would be enhanced if the fins were further extended to a point closer to the interior wall of the container.

Moreover, larger fins would increase the amount of surface area for heat transfer, giving an added advantage. On page 136 of the 1992 Wisniewski and Wu publication it states that the "fins length, thickness and shape were designed to maintain **efficient heat transfer** during freezing and thawing." (Emphasis supplied). It is not open to any serious debate that larger, thicker, fins that extend to points closer to the interior wall of the container are more efficient heat transfer vehicles than smaller, thinner fins that do not extend to points closer to the interior wall of the container.

The 1992 Wisniewski and Wu publication states on page 136: "The heat transfer fins were configured to **divide the tank into compartments** to decrease the freezing and thawing time and to reduce cryoconcentration effects. **Compartmentation** of the tank is especially effective for maintaining liquid in a static state to minimize cryoconcentration." (Emphasis supplied). The fins are designed to maintain "efficient

heat transfer during freezing and thawing" (page 134, col. 2, 1992 Wisniewski and Wu publication). Figure 1 (page 134) of the 1992 Wisniewski and Wu publication clearly shows heat transfer fins extending outwardly for the internal heat transfer coil towards the interior wall of the container. Extending the fins further outwardly to aid in the formation of compartments to minimize cryoconcentration would have been another motivation of compartments to minimize cryococentration would have been another motivation to one of ordinary skill in the art to make the same modification.

The 1986 Kalhori and Ramadhyani article by Wisniewski and Wu), like applicants have disclosed in Figures 1 & 2 of their drawings, shows in Figure 3 a "spur-tube" type heat exchanger with six heat transfer fins welded to it in a manner almost identical to what applicants show in Figures 1 and 2 of the current application. The finned heat exchanger as shown is immersed in a container of paraffin and the melting and freezing processes were studied in great detail with a material, paraffin, of known characteristics. See the abstract of this article on the first page. Again, fins that span nearly the entire interior of the container were found to be especially effective, with a host of definitive technical data presented (that is unnecessary to discuss here) showing the virtues of these large fins in improving heat exchange. See last sentence of article –"In view of the **superior heat transfer characteristics, the finned cylinder** is a much better choice of the design of a practical thermal storage unit." (Emphasis supplied).

In view of each of the above teachings, it would have been obvious to one of ordinary skill in the art to have extended the fins of the prior art disclosed in the 1992 article skill in the art to have extended the fins of the prior art disclosed in the 1992 article by Wisniewski and Wu to substantially the inner periphery of the container, leaving a small gap to permit the heat exchanger to be removed for cleaning (as is disclosed to be necessary in the 1992 article by Wisniewski and Wu page 136). Extending the fins to substantially the inner periphery of the container would:

- a. Improve heat transfer by increasing heat transfer surface area and
- b. Improves "compartmentation" by forming ice bridges.

In addition, to have replaced the centrally mounted heat exchanger and fins of the 1992 article by Wisniewski and Wu disclosed in Figure 1 with the heat exchanger and fins shown by Kalhori and Ramadhyani in Figure 3 to improve heat transfer and to facilitate ease of construction as well as to facilitate easy removal from the frozen mass would have been obvious to one of ordinary skill in the art.

Claims 96, 105-110, 112-115, 118 and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of the 1992 Wisniewski and Wu article and the 1986 Kalhori and Ramadhyani article as applied to claims 96, 105-110, 112-115, 118 and 119 above, and further in view Euwema (USP 3,550,393), Cothorn et

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al (USPN 5,535,598), West (USPN 2,114,642), Morrison (USPN 1,874,578) and Nakao (JP 57-58087).

Euwema discloses ice bridges forming at the ends of vanes 36 and 38 when wall 10 is cooled by a refrigerant. See column 3, lines 4-19. The ice is shown at 18 (Figure 1) and rapidly bridges the gap between the tips of vanes 36 and 38 and the cooled surface 10 of the refrigeration device (Figure 2) in much the same manner that applicants disclose in their specification with regard to ice forming in the gap between the tips of their fins 8 and the inner wall of their container. Euwema's ice divides the regions on either side of vanes 36 and 38 into separate compartments to facilitate improved heat exchange with the liquid in those compartments. In other words, the ice bridges in Euwema prevent the fluids in the compartments. In other words, the ice bridges in Euwema prevent the fluids in the compartments on either side of vanes 36 and 38 from intermixing in much the same manner that the 1992 publication by Wisniewski and Wu discusses is a desirable feature in their invention (see the 1992 publication by Wisniewski and Wu, page 136, first full paragraph – "The heat transfer fins were configured to divide the tank volume into compartments to decrease the freezing and thawing time and to reduce cryoconcentration effects").

Likewise, Cothorn et al teaches (Figures 1-3) a jacketed tank (Figure 2) similar to applicants and a fin-like heat exchanger formed with plates that divide the interior of the tank into a number of compartments by spanning nearly the entire tank to areas very

close (close spaced gaps) to the sidewalls of the tank (in much the same manner applicants disclose, albeit in a square tank as opposed to a round tank). These large heat exchanger plates provide great surface area for improved freezing as discussed by Cothorn in column 7, lines 46-52. In Cothorn, having these closely spaced gaps between the distal ends of the immersed heat exchanger and the walls of the jacketed tank permits the heat exchanger to be withdrawn easily for cleaning and reduces the need for tight manufacturing tolerances in the immersed heat exchanger fit tightly into the tank and form fully non-communicating compartments.

West in Figures 5 and 6 illustrates a fast freezing system which freezes the substance so fast that there are no cryoconcentration effects. See page 2, lines 60-66 and lines 70-72. The periphery of the heat exchanger structure 15 is clearly spaced from the container 8. In Figure 6 the freezing is applied to both the inside and outside of the container to further reduce cryoconcentration effects. See page 2, the last three paragraphs of the specification.

Morrison also teaches that fins 7 spanning nearly the entire interior of a container (which container is believed to be shown in phantom lines in Figure 1) "insure maximum heating or cooling is believed to be shown in phantom lines in Figure 1) "insure maximum heating or cooling surface, so that operation of the device may be carried out with facility" (Morrison, column 1, lines 8-13).

Finally, Nakao teaches metallic fins 5 spanning nearly the entire interior of a container having a phase-change material therein. A relatively small gap exists between the end of these fins and the wall of the container. These fins greatly aid in the transfer of heat introduced at, and removed from, the periphery of the container.

In view of each of the above teachings, it would have been obvious to one of ordinary skill in the art to have extended the fins of the prior art disclosed in the 1992 article by Wisniewski and Wu to substantially the inner periphery of the container, leaving a small gap to permit the heat exchanger to be removed for cleaning (as is disclosed to be necessary in the 1992 article by Wisniewski and Wu page 136).

Extending the fins to substantially inner periphery of the container would:

- a. Improve heat transfer by increasing heat transfer surface area as taught by Cothorn, West, Morrison, Nakao,
- b. Improve "compartmentation" by forming ice bridges as explicitly taught by Euwema and
- c. Eliminate cryoconcentration effects as taught by West.

In addition, to have replaced the centrally mounted heat exchanger and fins of the 1992 article by Wisniewski and Wu disclosed in Figure 1 with the heat exchanger and fins shown by Kalhori and Ramadhyani in Figure 3 to improve heat

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transfer and to facilitate ease of construction as well as to facilitate easy removal from the frozen mass would have been obvious to one of ordinary skill in the art.

Cothorn in column 7, lines 54 – column 8, line 8 teaches various controls for controlling both rate and cooling direction in a freeze container by varying refrigerant flow in the various portion of the device. To the extent that the system disclosed by applications can accomplish the functions set forth in the claims it would have been obvious to have the same end (those controls being broadly taught by Cothorn). Since applicants' own specification is virtually devoid of how these functions are accomplished it must be surmised that obtaining these results must be within the skill of those skilled in the refrigeration art.

Claims 96,105-110,112-115,118 and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the prior art as applied to claim 96,105-110,112-115,118 and 119 above, and further in view of the conceded prior art discussed on pages 1, line 22 - page 2, line 17 of the specification.

For the sake of completeness, even though the Examiner is unsure of the precise nature of applicant's admitted prior art, it appears that placing a heat exchanger structure with fins on it into a conditioned container is known however in this prior art the fins are attached to both the wall of the container and the heat exchange structure impossible. Such a deficiency however does not seem to be precluded by most of the

claims and even as to those which do claim non-attachment of the heat exchange structure to the tank wall, such a fairly taught by the 1992 Wisniewski and Wu article.

Claims 101, 111 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the prior art as applied to claims 88, 110 and 115 above, and further in view of Gross or Brown.

Brown (Fig 2) and Gross (Fig 24) each teach means forming spiral paths on the outside of a tank. To have configured the 1992 Wisniewski and Wu prior art with a spiral path on the outside of the tank would have been obvious to improve heat exchange.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to John Ford at telephone number 703-308-2636.


John K. Ford
Primary Examiner

14) ☐ Prior art(s)

15) ☐ Notice of Unpublished Ref. of Diagrams/Review (PTO 045)

17) ☐ Information Disclosed with respect to (PTO 1400) Paper Filed

18) ☐ Interview

20) ☐ Other